REMARKS/ARGUMENTS

The March 12, 2003 Office Action has rejected all claims under 35 U.S.C. § 112, double-patenting, claims 1 and 2 under 35 U.S.C. § 102 and all claims under 35 U.S.C. § 103. In light of the amendments above and the arguments below, Applicants respectfully request reconsideration.

Sequence Listing

On page 2 of the Office Action, the Examiner notes that no Sequence Listing has been filed. Applicants point to the filing of PCT/US00/00286, where a Sequence Listing was filed on January 6, 2000. Applicants have enclosed a document transferring the Sequence Listing from this PCT case to the above-identified U.S. application. If the Examiner needs a separate Sequence Listing filed in the above-identified U.S. application, Applicants will certainly provide one.

Page 2 of the Office Action notes that "this application does not contain an abstract . . . ." Applicants note that the original filing of the PCT/US00/00286 did contain an abstract, but to simplify matters Applicants have included the same abstract as an amendment to the present specification.

Claim Objections

Applicants have corrected the spelling of the word histocompatibility.

§ 112 Rejections

Claims 1 – 14 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Applicants have clarified claim 1 as to which epitope-specific CTL is meant.

On page 3 of the Office Action, the Examiner questions the language "in an amount sufficient to induce in the primate a cytotoxic T-lymphocyte response specific for the MHC class I restricted peptide epitope." Applicants believe that they have answered the Examiner's comment by their modification of the claim to specify that the immune specificity is focused on the peptide epitope and that the epitope and the viral polyepitope are from the same virus.

The Examiner questions the phrase "the sequence encoding." Applicants have corrected this typographical error.

The Examiner has objected to the phrase "a major histocompatibility complex class-I restricted peptide epitope." Applicants are in agreement with the Examiner's interpretation.

The Examiner has rejected claim 10 on the phrase "the primate's viral load." Applicants have amended claim 10 to specify that the vaccine is given to a human and that the human (who, according to claim 10 is subsequently exposed to the virus) becomes infected with the virus but has a viral load that is less than a human who was not vaccinated.

Claims 1 – 14 are rejected under 35 U.S.C. § 112, first paragraph. While neither agreeing nor acquiescing with the Examiner's reasoning, Applicants have amended claim 1 to be drawn to a response against a viral infection associated with a viral polyepitope and clarified that the viral polyepitope and the CTL epitope are from the same virus.

Double Patenting

The Examiner has rejected claims 1 and 2 as being unpatentable over claims 19 and 20 of co-pending application 09/434,830. Applicants have no access to application no. 09/434,830. It is neither published nor issued, so Applicants cannot comment on the specific

content of the application. However, Applicants have included the subject matter of claim 3, which is not rejected, in claim 1. Claim 2 has been cancelled.

§ 102 Rejection

Claims 1 and 2 are provisionally rejected under 35 U.S.C. § 102(e) as being anticipated by co-pending application no. 09/434,830. Applicants have no access to application no. 09/434,830. It is neither published nor issued, so Applicants cannot comment on the specific content of the application. However, Applicants have included the subject matter of claim 3, which is not rejected, in claim 1. Claim 2 has been cancelled.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(f). Applicants have no access to application no. 09/434,830. It is neither published nor issued, so Applicants cannot comment on the specific content of the application. However, Applicants have included the subject matter of claim 3, which is not rejected, in claim 1. Claim 2 has been cancelled.

§ 103 Rejection

Claims 1 – 13 are rejected under 35 U.S.C. § 103 as being unpatentable over Fuller, et al. (Immunol. Cell. Biol. 75:389-396, 1997) and Fuller, et al. (Vaccine 15:924-925, 1997), in view of Hanke, et al. (J. Gen. Virol. 79:83-90, 1998), Borgne, et al. (Virol. 240:304-315, 1998), and further in view of Loktev, et al. (J. Biotechnol. 44:129-137, 1996). The Examiner cites Fuller, et al. as teaching a nucleic acid vaccination method for SIV in a rhesus macaque combined with a live or recombinant vaccinia viral vector comprising a polynucleotide sequence expressing the SIV env epitope as a booster. The second Fuller, et al. reference is cited as teaching the appropriateness of boosting animals with either recombinant subunits or gp120 expressing recombinant vaccinia virus that could achieve synergistic responses and

dramatically improve antibody response. Hanke, et al. is cited as teaching a multi-CTL epitope and the importance of a CTL response. Borgne, et al. is cited as teaching induction of a specific CTL response to HIV with a DNA vector expressing an HIV epitope and a CTL epitope fused with HBsAg. As the Examiner points out, Borgne, et al. do not use a hepatitis B core antigen. Loktev, et al. is cited as teaching approaches to enhance the effectiveness of a molecular vaccine including expressing a peptide in a special protein-carrier such as HBsAg.

The Examiner summarizes, at the bottom of page 15 by stating that

> "Evidently, at the time of instant filing, using multiple dosing regimen and combining DNA vector with a viral vector in the HIV vaccination is well known in the art as taught by Fuller, et al., enhancing a CTL response to HIV with multi-CTL epitope and a hepatitis core antigen carrier are also well known in the art as taught by Hanke, et al., Borgne, et al., and Loktev, et al.; and it is also known that the CTL response to a polynucleotide encoding a HIV antigen, a multi-CTL epitope, and a hepatitis viral antigen are similar in mice and primates as taught by Borgne, et al. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by Fuller, et al., by simply combining various approaches known in the art with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the different approaches would result in a synergistic effect in enhancing the CTL response, thus the HIV vaccine efficacy. Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary."

Applicants note that the Examiner's references, either singly or combined, do not disclose a situation wherein at least 8.3% of $CD^{3+}/CD8\alpha^{+}T$ lymphocytes are specific for the epitope. The Examiner has opined that one would find a "synergistic effect" in combining elements of the prior art, but Applicants assert that the prior does not teach that the response would be at the level that Applicants have found. Applicants find support for this limitation at page 9, line 34 of the application.

Applicants have enclosed a Petition and Fee for Three Months Extension of time. If further fees are necessary, please charge Deposit Account 17-0055.

Respectfully submitted,

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